EXHIBIT A

U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 30, 2019

Via Email

John C. Bostic
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Kevin Downey
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Jeffrey B. Coopersmith
Orrick, Herrington & Sutcliffe, LLP
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Re: Document Request – *United States v. Elizabeth Holmes & Ramesh Balwani*, 18-CR-00258 EJD (N.D. Cal.)

Dear Messrs. Bostic, Downey, and Coopersmith:

I write to provide you an update on the status of the U.S. Food and Drug Administration's ("FDA") production of documents responsive to Defendants' motion to compel in the above-referenced case.

As set forth in detail in my September 23, 2019 letter to Mr. Bostic (Dkt. #121-2), FDA has taken great efforts to meet the Court-imposed deadlines to produce documents in this matter. Following the Court's July 19, 2019 Order ("Order"), FDA made productions on August 5, August 16, August 23, August 30, September 25, October 1, October 8, October 9,[1] and October 24, together totaling over 60,000 pages.[2] This production is in addition to the over 40,000 pages of documents that FDA produced to the U.S. Department of Justice ("DOJ") prior to the Court's Order that are in the possession of Defendants (*see* Dkt. #67, at 3).

FDA's September 23 letter explained that the agency anticipated that its October 1st production would include responsive, non-privileged documents from two buckets – (i) documents potentially responsive to the motion to compel categories that appeared to be unique, and (ii) documents potentially responsive to the motion to compel categories that, via a textual analysis, appeared to be duplicates of documents already in the

[1] FDA's October 8th and 9th productions consisted of documents identified to be responsive to Defendant Balwani's subpoena in the civil matter (18-cv-01603-EJD) that were nonetheless produced to the parties in this criminal matter pursuant to FDA's June 7, 2019 letter to the prosecution stating that, as FDA processed documents for the subpoena, it would provide those documents to the parties in this criminal matter (*see* Dkt. #79-4, at 2).

[2] This page count does not include pages that were produced with slipsheets stating "intentionally withheld" or "technical issue."

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possession of the parties, or duplicates of each other. FDA produced the responsive, non-duplicative, non-privileged documents from both buckets.

FDA's September 23 letter also explained that certain other documents would not be included in its October 1st production – (a) documents from FDA's Office of the Chief Counsel, (b) documents identified as containing foreign language or technical issues, and (c) a subset of documents from two custodians who were former employees, due to technical difficulties during collection. FDA's October 24th production contained documents from subsets (a) and (c). FDA's October 24th production also contained the foreign-language document from subset (b) and the technical-issue documents from subset (b) to the extent those technical issues were able to be corrected.

The following technical issues remain pending – some of which were identified following FDA's September 23 letter to the parties. FDA is working on resolving these issues as indicated:

- Approximately 40 stub files – FDA has requested that these files be restored from FDA's network, to the extent possible; afterwards, they will need to be re-loaded to the document review platform and then reviewed
- Approximately 1,114 partially-visible emails from custodian Alberto Gutierrez – there is no way to correct these email files. Accordingly, FDA is working to identify whether it has full versions of the emails from other custodians; to the extent it does not, it will produce the partially-visible emails
- An email container (.pst file) for custodian Katherine Serrano – FDA has requested that the files therein be restored from FDA's network; afterwards, they will need to be searched, loaded to the document review platform, and reviewed
- Approximately three documents with technical issues that have recently been corrected – FDA has reviewed and will produce.[3]

Additionally, FDA's collection, search, processing, and review for 14 additional custodians, requested by Defendants after the FDA's October 1st production, is ongoing.[4] FDA estimates that the documents from the 14 additional custodians will be loaded to the review platform by early December. Review time will depend on the volume of documents.

Finally, in response to the parties' meet and confer on October 23, 2019, FDA states as follows:

- Defendants' request for custodial documents from Agent for FDA's Office of Criminal Investigations ("OCI"): DOJ is handling production.

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[3] There exist approximately 10 documents with technical issues that cannot be fixed because the files are corrupt and 3 documents that are unreviewable because they require a connection to Theranos.com.

[4] FDA is also reviewing approximately 255 documents from custodian Alberto Gutierrez that recently came to the attention of undersigned counsel.

FDA U.S. FOOD & DRUG ADMINISTRATION

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- Defendants' request to confirm that document collection extended beyond email files, to include network files, hard copy files, and text messages: We have reached out to the custodians and/or FDA's information management personnel and will circle back to Defendants. To the extent additional documents are identified, FDA will process, review, and produce as soon as practicable.
- Defendants' request for confirmation that documents subject to a litigation hold, for employees who departed following the issuance of that hold, were preserved: FDA's information management personnel possesses, and has not deleted, all electronic documents for custodians who departed following the issuance of the litigation hold, mirroring what was in the custodians' possession at the time of departure. We are looking into the preservation of hard copy documents and will circle back with Defendants.
- Defendants' search string for category 1 documents: FDA confirms that there was a typo in the email to Defendants for that search string but not in the search string itself. The correct search string is: Theranos* AND (John.Carreyrou@dowjones.com OR dowjones.com OR WSJ OR "Wall Street Journal" OR "212-416-2309" OR "917-536-7824" OR Carreyrou)
- Defendants' concern with documents slipsheeted as "intentionally withheld": Documents slipsheeted as "intentionally withheld" are non-responsive, entirely privileged, or duplicative of other documents. We received a list from Defendant Balwani's counsel of particular "intentionally withheld"-slipsheeted documents that it wants FDA to re-produce in full. FDA will review the list and circle back with Defendants about these documents.
- Defendants' concern with the search terms utilized to identify documents potentially responsive to categories 2 and 4:
    - With respect to Defendants' contention that the search term "waiver" should have been included for category 2, a "CLIA Waiver" is unrelated to Theranos's CLIA compliance. CMS regulates compliance with the Clinical Laboratory Improvement Amendments ("CLIA") by conducting surveys of laboratories. CMS grants certificates of waiver for laboratories that only perform waived tests. FDA determines whether tests fall into the waived test category. Waived tests include simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. Laboratories that conduct only waived tests are not generally subject to routine CMS surveys, but may be subject to CMS surveys for cause. Laboratories must comply with CLIA whether an individual test has received a CLIA waiver or not. Accordingly, CLIA compliance is unrelated to a CLIA waiver. *See also* Dkt. #67, at 16-18 (Defendants explaining that category 2 is geared toward CMS's CLIA Surveys). The search string run by FDA for category 2 was: ((Theranos* AND ("Clinical Laboratory Improvement Amendments" OR CLIA) AND compl*) AND NOT Waiver) OR (Theranos* AND ("Clinical Laboratory Improvement Amendments" OR CLIA) and Survey)
    - With respect to Defendants' contention that "LDT" should have been included for category 4, FDA's search for category 4 is appropriately geared toward the types of FDA approval and/or clearance for devices such as

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those at issue in this case. The term "LDT" appears nowhere in the indictment or in Defendants' motion to compel. Defendants additionally contend that they should have received documents relating to laboratory developed tests ("LDTs") generally, whether or not they relate specifically to Theranos. That interpretation is inconsistent with the text of category 4 and finds no support in the arguments Defendants made in the motion to compel. The search string run by FDA for category 4 was: Theranos* AND (Clearance OR PMA OR "premarket approval" OR "De novo" or "Humanitarian Device Exemption" OR HDE OR "510(k)" OR "510k" OR "Investigational device exemption" or IDE OR "K152647" OR "K152965" OR "K152971" OR "Q151162" OR "Q151964" OR "Q160388" OR "Q160470" OR "K143236" OR "CW150009")

- Defendants' concern that there are purportedly fewer than expected documents for the year 2014: FDA searched for documents for the timeframe January 2010 through June 2018; that search was sufficient to capture documents in the year 2014.
- Defendants' concern with FDA's redactions for the law-enforcement privilege: FDA explained that it is possible that some such redactions were unrelated to Theranos. To the extent Defendants continue to have questions, they will provide a list of those documents to FDA. FDA will also voluntarily undertake a targeted re-review of those redactions.
- Defendants' concern with FDA's redactions for non-responsiveness and the deliberative process privilege: FDA explained that, for documents, or portions of documents, that were not responsive to the six motion to compel categories, it identified them as "non-responsive," which, in turn, was able to save the agency valuable review time that it otherwise would have had to spend to identify other applicable redactions to the non-responsive portions (such as, for example, third-party trade secret and confidential commercial information, which the agency is prohibited by law to produce absent a waiver from that third-party). As this material is non-responsive, there is no harm to Defendants. Additionally, FDA reiterated that it waived its deliberative process privilege with respect to Theranos-specific documents, but not as to non-Theranos-specific documents. The agency's deliberative process privilege redactions comply with the terms of the waiver.
- Defendants' request for a privilege log: FDA will circle back with Defendants regarding this request after the close of its review and production of documents.
- Defendants' request for additional metadata to accompany FDA's productions: FDA will provide the additional metadata for its October 9 production. Otherwise, FDA has already provided the additional metadata to the parties for its remaining non-manual productions.

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FDA continues to work diligently and in good faith to provide the parties with the documents responsive to the motion to compel.

Sincerely,

Marci B. Norton

Marci B. Norton
Senior Counsel